UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,763	11/20/2003	Ron L. Hale	00064.01R	3281

37485 7590 06/27/2007
SWANSON & BRATSCHUN, L.L.C
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,763	HALE ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/04,6/24/05 and 2/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment and remarks submitted on May 16, 2007. Claims 1-38 are pending in the application, with claims 1-31 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 32-38 are being examined on the merits herein.

It is further noted that the claims are being examined only to the extent they read on the elected species of antipsychotic that is a phenothiazine antipsychotic.

Priority

Applicant's claim of priority to U.S. Provisional Application Serial No. 60/429,404 filed November 26, 2002, is acknowledged.

Election/Restrictions

Applicant's election without traverse of the claims of Group II, namely claims 32-38, in the reply filed on May 16, 2007 is acknowledged. Applicants' election without traverse of the species of antipsychotic that is a phenothiazine antipsychotic in the same reply is also acknowledged.

The restriction requirement is still deemed proper and is made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Frank S. Caruso, issued April 6, 1999.

Caruso teaches methods and compositions for the treatment of migraine headaches. Caruso teaches that preferred compositions include an anti-migraine agent in combination with a NMDA receptor blocker (see column 2, lines 25-35, in particular.) Caruso teaches that compounds that also assist in blocking the consequences of NMDA receptor activation, and that are thus also suitable for use in the anti-migraine composition in addition to or in place of the NMDA receptor blocker include phenothiazines, such as chlorpromazine and prochlorperazine (see column 3, lines 53-65, column 4, lines 10-35 and 49-65, and column 5, lines 9-20, in particular.) Thus, Caruso teaches providing the antipsychotic phenothiazine compounds as recited in claims 32-34 for the treatment of migraine headaches.

Caruso does not specifically exemplify a "kit" having the phenothiazine antipsychotic and an inhalation delivery device, as recited in claim 32.

However, Caruso does teach that such anti-migraine compositions can be therapeutically delivered via inhalation means, such as via a pressurized pack or a nebulizer (see column 6, lines 62-66, in particular.) Caruso also exemplifies an anti-migraine composition in inhalation dosage form (see Example 12, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the anti-migraine composition having the phenothiazine antipsychotic via inhalation means, and thus to provide a "kit" having the composition and an inhalation device, such as a pressurized aerosol pack or nebulizer, because Caruso teaches the antipsychotic phenothiazine is suitable for the treatment of migraines, and also teaches that anti-migraine compositions can be therapeutically administered via inhalation. Thus, one of ordinary skill in the art would have been motivated to provide a "kit" having the anti-migraine composition containing the phenothiazine antipsychotic and an inhalation delivery device, with the expectation of providing a device suitable for the therapeutic treatment of migraines. Accordingly, claims 32-34 are obvious over the teachings of Caruso.

Regarding claim 35, it is noted that Caruso teaches that the potentiating agent must be present in an amount that potentiates the effectiveness of the anti-migraine drug (see column 5, lines 38-60, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phenothiazine antipsychotic provided in the composition, according to the guidance provided by Caruso, to provide a composition having desired potentiation of the anti-migraine drug. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 36, it is noted that Caruso teaches that capsules and cartridges can be formulated for use in inhalers containing the composition (see column 7, lines 1-10, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phenothiazine antipsychotic provided in a capsule or cartridge composition, and to provide more than one such capsule or cartridge with different dosages, according to the guidance provided by Caruso, to provide a desired anti-migraine treatment regimen with the inhalation device. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Frank S. Caruso, issued April 6, 1999, as applied to claims 32-36 above, and further in view of U.S. Patent No. 5,699,789 to Mark R. Hendricks et al, issued December 23, 1997.

Caruso is applied as discussed above, and renders obvious a "kit" having an inhalation device and an anti-migraine composition containing an phenothiazine antipsychotic.

Caruso does not specifically teach providing instructions for use in the kit, as recited in claim 37.

Hendricks teaches that it is known to include instructions for use with an inhaler for the delivery of pharmaceutical compositions (see column 7, lines 54-61, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide instructions for use, as taught by Hendricks, with the inhalation "kit," as taught by Caruso, with the expectation of providing components that render the inhalation device and compositions suitable for therapeutic use.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Frank S. Caruso, issued April 6, 1999, as applied to claims 32-36 above, and further in view of U.S. Patent No. 5,743,251 to Howell et al, issued April 28, 1998.

Caruso is applied as discussed above, and renders obvious a "kit" having an inhalation device and an anti-migraine composition containing a phenothiazine antipsychotic.

Caruso does not specifically teach that the inhalation device is capable of producing a condensation aerosol, as recited in claim 38.

Howell et al. teaches an aerosol generating apparatus suitable for inhalation administration of pharmaceutical compositions (see abstract and column 1, lines 1-35, in particular.) Howell et al. teaches that the particular apparatus taught therein is capable of volatilizing a material, which then condenses to form an aerosol (see abstract, in particular.) Accordingly, Howell et al. is considered to teach an inhalation device capable of forming a condensation aerosol for therapeutic administration.

Accordingly, it is considered that one of ordinary skill in the art at the time of the invention would have been motivated to provide the condensed aerosol forming

inhalation device of Howell et al. in the "kit" of Caruso, because Caruso teaches that the anti-migraine compositions can be administered via inhalation, in general, and Howell et al. teaches a device that is suitable for the inhalation administration of therapeutic compositions. Thus, one of ordinary skill in the art would have been motivated to provide the condensed aerosol forming inhalation device of Howell et al. as the inhalation device for the administration of the anti-migraine composition of Caruso, with the expectation of success in providing a device capable of delivering the anti-migraine composition via inhalation to effect treatment of migraines.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 32-38 are provisionally rejected for statutory type double patenting over claims 32-38 of U.S. Patent Application Serial No. 11/346,548 as published in U.S. Patent Application Publication No. 2006/0193788 to Hale et al, published August 31,

2006. The instant and published claims are identical, and thus the instant claims are rejected for statutory type double patenting over the conflicting claims.

This is a provisional statutory-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of U.S. Patent No. 7,090,830 to Hale et al, issued August 15, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to

a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a kit having a particular inhalation device and a drug, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the patented claim, and are not patentably distinct over claim 27 of U.S. Patent No. 7,090,830.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-27 and 43-62 of U.S. Patent No. 7,078,020 to Rabinowitz et al, issued July 18, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a kit having a particular inhalation device and a drug, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the patented claims, and are not patentably distinct over claims 20-27 and 43-62 of U.S. Patent No. 7,078,020.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/633,877 as published in U.S. Patent Application Publication No. 2007/0031340 to Hale et al, published February 8, 2007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine

antipsychotic, and the conflicting claims are drawn to an article for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over claim 9 of copending U.S. Patent Application No. 10/633,877.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/633,876 as published in U.S. Patent Application Publication No. 2007/0028916 to Hale et al, published February 8, 2007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to an assembly for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over 26 of copending Application No. 10/633,876.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of copending Application No. 11/488,932 as published in U.S. Patent Application Publication No. 2006/0280692 to Rabinowitz et al, published December 14, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a kit for aerosol delivery having a device for dispensing an aerosol, and a coating of a drug for dispensing, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over 27 of copending Application No. 11/488,932.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 11/248,598 as published in U.S. Patent Application Publication No. 2006/0120962 to Rabinowitz et al, published June 8, 2006. Although the conflicting

claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a particular type of inhalation device having a dosage of drug, where the drug can be prochlorperazine, an phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over claim 9 of copending Application No. 11/248,598.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

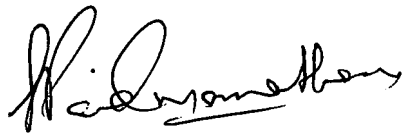
The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is cited in the accompanying PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER